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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/944,326	08/30/2001	Martin Gleave	UBC.P-020-2	2324

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EXAMINER	
VIVLEMORE, TRACY ANN	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 08/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/944,326	GLEAVE ET AL.	
	Examiner	Art Unit	
	Tracy Vivlemore	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 May 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,12-15,19,23-26 and 28-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,19,23,28 and 30* is/are rejected.

7)☒ Claim(s) *12-15,24-26 and 29* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *5/30/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

The information disclosure statement filed May 30, 2006 that duplicates the IDS of March 18, 2005 has been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim depends from claim 1 and recites a composition that comprises SEQ ID NO: 4 and has a length of 18-21 bases. The metes and bounds of this claim cannot be determined because it is unknown how a composition can be 18, 19 or 20 nucleotides in length and comprise SEQ ID NO: 4, which is 21 nucleotides in length.

Response to arguments: Double Patenting

Claims 1 and 19 remain rejected and new claim 30 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim

1 of U.S. Patent No. 6,900,187 for the reasons set forth in the office action mailed July 28, 2005.

Applicant traverses the double patenting rejection by noting that the patent issued from a later filed application and a two-way analysis is appropriate. However, as stated in the office action of October 29, 2004, a two-way test of obviousness is required only when there is administrative delay on the part of the Office causing delay in prosecution of the earlier filed application.

Applicant further traverses the rejection by stating that the PCT counterpart of the instant application was of record and must have been considered by the examiner of the '187 patent. This argument is not persuasive because each application is considered separately and no comment regarding the prosecution of another application can be made. Applicant also asserts "the examiner has offered no reasons why the standard of obviousness is met." While this statement is unclear because it is unknown what standard of obviousness applicant refers to, applicant appears to be arguing that the examiner has not offered reasons why the instant claims and the patent claims are obvious variants. These reasons were set forth in the office actions mailed on February 17, 2004 and July 28, 2005. Because the sequence in both the instant and patented claims is identical, the species with modifications that is claimed in the patent is an obvious variation of the generic claim of the instant application.

Response to arguments: Claim Rejections - 35 USC § 103

Claims 1 and 23 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al. in view of Baracchini et al. for the reasons set forth in the office action mailed July 28, 2005.

Applicant traverses the 103 rejection by arguing that the examiner has provided no evidence that a person skilled in the art has ever interpreted the term oligonucleotide in a manner that would encompass sequences of 1300 base pairs. Applicant further states that no definition of this term that is of record refers to any sequence this large as an oligonucleotide or defines oligonucleotide as being small relative to something else. Applicant appears to have misunderstood the examiner's point regarding the comparison of a sequence of 1300 base pairs with a sequence of 6000 base pairs and it will be clarified. In the remarks filed on September 28, 2005, applicant argued that the cDNA of Wong et al. could not be considered an oligonucleotide because oligonucleotides are short nucleotide sequences. In support of this argument applicant provided a definition of oligo: "oligo is an abbreviation of oligonucleotide, which is a short sequence of nucleic acids (generally fewer than 100 bases)." The examiner disagreed with applicant's arguments because the term oligonucleotide is not defined absolutely in the art. The definition provided by applicant uses the relative term "short". The examiner's statements regarding a comparison between two sequence lengths were used to illustrate how short is a relative, rather than absolute, term. It was not meant to redefine an oligonucleotide as being small relative to something else, but to illustrate that because "short" is a relative term anything defined as "short" must be in

comparison to other things. Absent a definition of the term oligonucleotide that excludes sequences over a certain length, the cDNA of Wong et al. is considered to fall within the term oligonucleotide.

Applicant states that additional definitions of this term and references that are inconsistent with the examiner's position are enclosed, however such material is not present in the application file.

Applicant argues that the teaching of Wong et al. that TRPM-2 "is associated" with various diseases is at best an invitation to experiment and does not render any particular thing obvious. This argument appears to be saying there is no motivation to combine the Wong and Baracchini references. The teaching in Wong of TRPM-2 being over-expressed in disease states provides the person of ordinary skill in the art with a motivation to make a composition comprising the TRPM-2 sequence taught by Wong and is not an invitation to experiment.

Allowable Subject Matter

Claims 12-15, 24-26 and 29 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on 571-272-4517. The central FAX Number is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image

problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see http://pair-direct.uspto.gov.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tracy Vivlemore
Examiner
Art Unit 1635

TV
August 1, 2006

TC1600

JANE ZARA, PH.D.
PRIMARY EXAMINER